

### **REMARKS**

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Applicants have amended claims 6, 15, 21, and 22. Support for these amendments can be found throughout the specification, including at Example 2, page 14, line 22. No new matter has been added through the amendments.

Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. §§ 102(b) and 103(a).

#### **Rejection under 35 U.S.C. § 102(b)**

The Examiner rejects claims 6 and 8 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,436,996 B1 (Vitek *et al.*). In particular, the Examiner cites claim 1, col. 9, lines 3-8 as allegedly anticipatory, which is reproduced below.

...wherein said exogenous source of nitric oxide is selected from the group consisting of nitroglycerine, L-arginine, nitrate esters, isoamyl nitrite, S-nitro-N-cysteine (SIN-1); and, cysteine, dithiothreitol, N-acetylcysteine, mercaptosuccinic acid, thiosalicylic acid, and methylthiosalicylic acid.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully traverse this rejection.

In the Advisory Action of March 24, 2008, the Examiner asserts that claim 1 recites two Markush groups:

1. nitroglycerine, L-arginine, nitrate esters, isoamyl nitrite, S-nitro-N-cysteine (SIN-1); and
2. cysteine, dithiothreitol, N-acetylcysteine, mercaptosuccinic acid, thiosalicylic acid, and methylthiosalicylic acid.

Applicants respectfully assert that the basis of this rejection, the two Markush groups, is erroneous. As stated in MPEP 2173.05(h):

One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

Applicants respectfully assert that claim 1 of the '996 patent does not recite the language required for two Markush groups. A claim reciting two Markush groups would recite "selected from the group consisting of A, B and C, and selected from the group consisting of A, B and C." Claims one only recites "selected from the group consisting of" once. The alleged second Markush group does not recite "selected from the group consisting of", thereby not containing the required Markush language. Also, claim 1 only recites "and" twice. If there are two Markush groups, each group should contain an "and" in each grouping in addition to an "and" separating the two groups. Since claim 1 does not properly cite two Markush groups, the claim requires only one compound to be selected.

The specification of the '996 application does not enable a composition comprising the two Markush groups. Nowhere in the specification do Vitek et al. disclose a composition selected from those two Markush groups. There is no support or reason for separating out those compounds into the separate groupings. Applicants have also analyzed the prosecution history of the '996 patent. There is also no support in the file history to support a composition comprising the two alleged Markush groups. Applicants respectfully assert that the disclosure of Vitek et al. do not enable a composition of more than one compound recited at col. 3, lines 32-38.

The Examiner's interpretation of two Markush groups is inconsistent with the language that defines a Markush group, with the specification, and the file history.

In view of the foregoing, Applicants respectfully assert that claims 6 and 8 are not anticipated by the '996 patent since the recitation characterized as two Markush groups is not in fact two Markush groups and even if they were two Markush groups, the specification of the

'996 patent does not enable such a composition. Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 102(b).

**Rejections under 35 U.S.C. § 103(a)**

The Examiner rejects claims 6, 8-17, 21-25, and 31 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. 6,436,996 B1 (Vitek *et al.*) in view of Mattia *et al.*, *Dibetologia*, 1998, 41:1392-1396 and further in view of WO 00/19992 (Lautt *et al.*). Applicants respectfully traverse the rejection under 35 U.S.C. § 103(a).

To make a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, 127 S. Ct. 1727 (2007). To make a *prima facie* case of obviousness, "it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." *Id.*

Again, Applicants respectfully assert that there is not a disclosure in the specification or the file history to support a composition comprising a nitric oxide source selected from the group consisting of one group of compounds and then another group of compounds.

As discussed above, the '996 patent does not disclose two Markush groups. As defined by the MPEP, claim 1 of the '996 patent is missing recitations of a second "selected from the group consisting of" and an "and" in the alleged first Markush group. Since claim 1 does not properly cite two Markush groups, the claim requires one compound to be selected. This interpretation is consistent with the specification and file history.

The Examiner's interpretation of two Markush groups is inconsistent with the language

that defines a Markush group, with the specification, and the file history.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 103(a).

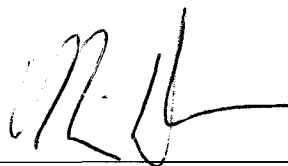
**Summary**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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